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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,125

11/18/2003

Jun Kashimura

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EXAMINER

ORWIG, KEVIN S

ART UNIT

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1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/715,125	Applicant(s) KASHIMURA ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 19-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date | 6) <input type="checkbox"/> Other: _____ |

4/9/04, 9/16/05, 2/3/06, 5/10/06, 8/16/06, 5/7/07, 12/5/07.

DETAILED ACTION

Response to Amendments/Arguments

Applicants' amendments and arguments filed Oct. 16, 2008 are acknowledged and have been fully considered. Applicants' arguments are moot in light of the new grounds of rejection set forth below. Claims 1-28 are currently pending. Claims 1-18 are the subject of this Office Action.

The rejection of claims 1-11 and 13-17 under 35 U.S.C. 102(b) over MENTINK is withdrawn upon further consideration.

The rejection of claims 7, 12, 13, and 18 under 35 U.S.C. 103(a) is withdrawn upon further consideration.

Applicants' arguments, see p. 12-14 of the response, filed Oct. 16, 2008, with respect to the rejection(s) of claim(s) 1-18 under U.S.C. 102(b) and 103(a) have been fully considered and are persuasive. The examiner agrees that PALATINOSE and hydrogenated isomaltulose are distinct chemical entities. Further, applicants' definition of PALATINOSE found in paragraphs [0057] and [0058] of the pre-grant publication excludes the interpretation that hydrogenated isomaltulose (i.e. hydrogenated PALATINOSE) is a species of PALATINOSE. Therefore, the previous rejections have been withdrawn. However, upon further consideration, new ground(s) of rejection are

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made in view of the newly applied prior art references, discussed below, which explicitly teach isomaltulose and the other elements required by the instant claims.

New grounds of rejections for claims 1-18 are set forth below.

Status of the Claims

Claims 1-28 are currently pending. Claims 1-18 are the subject of this Office Action. Non-elected claims 19-28 have been withdrawn from consideration.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

New Grounds of Objections/Rejections

Specification

The use of the trademark PALATINOSE™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology (e.g. isomaltulose).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-18 contain the trademark/trade name PALATINOSE®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a limiting component of the claimed compositions and, accordingly, the identification/description is indefinite.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be **Nov. 18, 2003**, the filing date of the instant application. It is noted that the effective U.S. filing date specified in the prior Office action was in error. The prior Office action stated:

"The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be November 18, 2002, the filing date of application JAP-2002-334023.

This determination is incorrect. It is noted that the *foreign priority date* and the effective *U.S. filing date* are distinct. The date of a foreign priority document can never be used as a U.S. filing date. See MPEP § 706.02 (see subsection VI. Determining the effective filing date of the application, item (C)).

Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of the Japanese applications were filed with the USPTO on Apr. 9, 2004. In the case that an intervening reference is applied in a rejection, applicants will be entitled to the foreign priority date for the purpose of overcoming the date of the reference, provided that a certified English language translation is supplied and it is determined that the corresponding foreign application supports the claims in the manner required by 35 U.S.C. 112, first paragraph. See MPEP § 201.15. See MPEP § 201.15, which states "The only times during *ex parte* prosecution that the examiner considers the merits of an applicant's claim of priority is when a reference is found with an effective date between the date of the foreign filing and the date of filing in the United States and when an interference situation is under consideration."

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims, as written, do not sufficiently distinguish over compositions comprising isomaltulose as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed blood glucose level increase reducer and the naturally occurring compositions. The claimed reducer of blood glucose level increase reads upon naturally occurring honey and sugarcane (see paragraph [0059] of the instant specification), both of which comprise sucrose and can be considered foodstuffs.

In the absence of the hand of man, naturally occurring compositions (e.g. honey and sugarcane) are considered non-statutory subject matter (*Diamond v. Chakrabarty*, 206 U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (*Ex parte Siddiqui*, 156 U.S.P.Q. 426 (1996)). However, when purification results in a new utility, patentability is considered (*Merck Co. v. Chase Chemical Co.*, 273 F. Supp 68 (1967), 155 U.S.P.Q. 139, (District Court, New Jersey, 1967)). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified”, or similar language that is properly supported by the instant disclosure. See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by LINA (Lina, B. A. R., *et al.* (2002). Food and Chem. Tox. 40(10); 1375-1381; published online May 2, 2002).

1. Lina teaches that isomaltulose (i.e. PALATINOSE[®]) is a natural occurring disaccharide that has been used as a sugar in Japan since 1985 (abstract). Lina teaches that isomaltulose is particularly suitable as a non-cariogenic sucrose replacement in products for diabetics, in part because blood glucose levels in humans after oral administration of isomaltulose are attenuated compared to sucrose administration (abstract; p. 1377, left column, 1st full paragraph; p. 1379, left column, 2nd paragraph). Lina teaches the use of isomaltulose as an alternative sugar in most sweet foods (abstract; p. 1375, right column, middle paragraph). Lina also teaches compositions comprising both isomaltulose and sucrose (i.e. wherein the two compounds are administered simultaneously) (p. 1377, right column, last paragraph).

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2. It is noted that the "wherein" clauses in claims 1-11 and 13-17 are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an α -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

3. Additionally, claims 7, 12, and 13 require the presence of a foodstuff composed of a carbohydrate "having an α -1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides." This recitation embraces carbohydrates having 0% of the recited ratio (i.e. carbohydrates which do not have any α -1,6-glucosyl bonds). Thus *any* carbohydrate (e.g. sucrose) meets the claim.

4. It is further noted that the ability of isomaltulose to reduce an increase in blood glucose level, or reduce body fat accumulation is an inherent property of the compound. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

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See MPEP 2112.01. Thus, any composition comprising isomaltulose would have this property and reads on the claims. Claims 1-9 and 13-15 are anticipated by Lina.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by BUCKE (U.S. 4,587,119; Issued May 6, 1986).

5. Bucke discloses the use of isomaltulose as a whole or partial replacement for sucrose in food products for human or animal consumption (abstract). Bucke teaches the use of isomaltulose in premixes, such as cake mixes and in beverages (col. 2, lines 4-14; col. 4, lines 32-39). Furthermore, Bucke discloses several embodiments in which the food material comprises an isomaltulose weight ratio of 10% or more relative to the total weight of the carbohydrate in the food material (e.g. Examples 1, 3, 4, 5). Bucke anticipates claims 1-18.

6. It is noted that the "wherein" clauses in claims 1-11 and 13-17 are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an α -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

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7. Additionally, claims 7, 12, and 13 require the presence of a carbohydrate "having an α -1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides." This recitation embraces carbohydrates having 0% of the recited ratio (i.e. carbohydrates which do not have any α -1,6-glucosyl bonds). Thus any carbohydrate (e.g. sucrose) meets the claim.

Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by BRENDel (U.S. 2002/0192344; Filed Mar. 29, 2002).

8. Brendel discloses processes for preparing food products with reduced calorific value by replacing the high-calorie substances in the food produces with related substances of reduced calorific value (abstract). Brendel teaches the use of isomaltulose as a replacement for sugars in food products such as biscuits (paragraphs [0026] and [0030]-[0032]; claim 9). Brendel teaches the use of isomaltulose along with maltodextrins and/or starches such as wheat flour (i.e. carbohydrates having an α -1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides as defined in paragraph [0062] of the instant specification). Brendel teaches that isomaltulose may comprise 0.5-98% by weight (relative to the total weight of the foodstuff, which represents a weight ratio of at least 10% or more relative to the carbohydrate contained in the food (paragraphs [0026] and [0030]-[0032]; claim 9; Examples 1, 4 and 6).

9. It is noted that the "wherein" clauses in claims 1-11 and 13-17 are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer

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is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an α -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643